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09/380,826	11/22/1999	RODERICK J. CHAPPEL	DAVIE79.001A	3117

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/12/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/380,826

Applicant(s)

CHAPPEL

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-14, 19, 20, 75 and 124-127 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14, 19, 20, 75 and 124-127 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Amendment Entry***

1. The amendment filed October 1, 2003 has been entered. Claims 1 and 19 have been amended. Claims 15-18 and 21-74 and 76-123 have been cancelled. Claim 127 has been added. Claims 1-14, 19-20, 75 and 124-127 are under consideration in the office action.

***Withdrawn Rejections***

2. The following rejections have been withdrawn in view of applicants' amendments:
- a) The written description and new matter rejections of claims 1-14, 19-20, 75 and 124-127 under 35 U.S.C. 112, first paragraph; and
  - b) The rejection of claims 1-20, 75 and 124-126 under 35 U.S.C. 112, second paragraph.

***Response to Arguments***

3. Applicant's arguments filed October 1, 2003, have been fully considered however they are not found persuasive.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The written description rejection of claims 1-14, 19-20, 75 and 124-127 under 35 U.S.C. 112, first paragraph is maintained.

Claim 1 in particular is drawn to an isolated pathogenic *Leptospira* bacterium comprising a generic sequence selected from the group consisting of a) SEQ ID NO:1; a sequence having at least 99% identity to SEQ ID NO:1; and a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684.

The maintenance of the rejection is on the grounds that the specification does not provide evidence of a *Leptospira* bacterium comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. Applicants have not shown a bacterium with the recited features.

The specification at pages 4 and 5 define the term serovar and serogroups but do not teach the identity of an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. The specification fails to state the identity of a cross-reactive strain that has the claimed growth characteristics or the claimed ability to infect. Applicants also point to example 4 that describes an agglutination assay, however the example fails to teach

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the identity of the isolated bacterium to which the claims are drawn. Therefore, applicant is attempting to claim a bacterium of which they did not have possession.

The skilled artisan cannot envision the detailed structure of the isolated bacterium, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention. The bacterium itself is required. The growth characteristics and infection activity distinguishes the claimed bacterium strain only by what it does, i.e., by growth and infection, which are purely functional distinctions. Even where there is an actual reduction to practice, which may demonstrate possession of an embodiment of an invention, it does not necessarily describe what the claimed invention is. The instant specification and claims describe an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684 isolated bacterium by its function i.e., growth and infection abilities, however this description does not describe the claimed bacterium itself.

Applicants' point to different pages throughout the specification including pages 4, 8, 10-11, 18-19, 42 and example 4 in support of their argument that the specification teaches the identity of the isolated pathogenic *Leptospira* bacterium. However, none of the recited sections recite a *Leptospira* bacterium comprising a sequence

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complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. At best, the specification points to evidence that other bacterial species exist yet they have not yet been identified and/or classified into the stated servovars. In view of the lack of evidence, it is apparent that Applicants' were not in possession of an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684 at the time of filing the instant application that meets the claimed definition.

Applicants' arguments fail to be persuasive, since applicants have failed to identify a bacterium that meets the claims limitations. Thus, in the absence of an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684 the full breadth of the claims fail to meet the written description provision of 35 USC 112, first paragraph.

5. The new matter rejection of claims 1-14, 19-20, 75 and 124-127 under 35 U.S.C. 112, first paragraph is maintained.

The rejection is maintained on the grounds that neither the specification nor originally presented claims provides support for an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684.

The specification fails to state the identity of an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to SEQ ID NO:1 or a sequences with 99% identity to SEQ ID NO:1 wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. Applicants have failed to point to a bacterium that meets the limitations of the claims. None of the examples teach the identity of the isolated bacterium to which the claims are drawn. There appears to be no teaching of an isolated pathogenic *Leptospira* bacteria with the claimed characteristics. Therefore, the new claims incorporate new matter and the rejection is maintained.

Contrary to applicants' argument, applicants' did not point to support in the specification for an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with

the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. As previously addressed applicants' pointed to various pages throughout the specification, however there appears to be no support for an isolated pathogenic *Leptospira* bacterium comprising genetic sequence comprising a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684.

6. The enablement rejection of claims 1-14, 19-20, 75 and 124-127 under 35 U.S.C. 112, first paragraph, is maintained for reasons already of record.

The claims are drawn to an isolated pathogenic *Leptospira* bacterium comprising a generic sequence selected from the group consisting of a) SEQ ID NO:1; a sequence having at least 99% identity to SEQ ID NO:1; and a sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684.

The rejection is maintained because the specification still fails to teach the identity of an isolated pathogenic *Leptospira* bacterium comprising a generic sequence complementary to SEQ ID NO:1 or with 99% identity to SEQ ID NO:1 wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. Thus, the specification fails to enable an isolated pathogenic *Leptospira* bacterium with the claimed



characteristics. The specification lacks any written description of an isolated pathogenic *Leptospira* bacterium comprising a generic sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684. There are no representative polynucleotides encoding a representative polypeptide sufficient to allow one skilled in the art to determine that the inventor had possession of the invention as claimed.

Such experimentation requires ingenuity beyond that expected of one of ordinary skill in the art. Such need for non-routine experimentation demonstrates that the specification is not enabled for any asserted use or well-established use of an isolated pathogenic *Leptospira* bacterium comprising a generic sequence complementary to one of the foregoing sequences wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession NO. N95/69684.

Contrary to applicants' assertion, applicants' have failed to point to working examples containing the missing information. Without such information, one of skill in the art would have to de novo isolate the bacterium. Accordingly, one of skill in the art would be required to perform undue experimentation to produce such isolated bacterium. Therefore the rejection is maintained.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 127 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 127 recites the phrase "sufficient homology " however it is unclear how to define "a genetic sequence having sufficient homology with SEQ ID NO:1". The rejection is on the grounds that the specification does not teach how to define what level of homology is sufficient. The language is vague and indefinite because the amount of homology needed to determine whether an unknown genetic sequence could be considered to have sufficient homology with SEQ ID NO:1 is unknown. The specification fails to disclose a definition for "sufficient homology", nor does it teach a requisite amount of homology needed to determine sufficiency. Therefore the claims are unclear.


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines   
December 4, 2003

  
NITA MINNIFIELD  
PRIMARY EXAMINER  
12/10/03